

TMH/SWR:dm 07/25/06 4630-66461-04 538912 672

PATENT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re application of: Chew et al.,

Application No. 10/565,717~

Filed: January 23, 2006 Confirmation No. 7940

For: NATURAL ASTAXANTHIN EXTRACT

REDUCES DNA OXIDATION

Examiner:

**Art Unit:** 

Attorney Reference No. 4630-66461-04

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Attorney or Agent for Applicant(s)

Date Mariled July 25, 2006

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Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent.

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Respectfully submitted,

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BY APPLICANT

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First Named Inventor	Chew
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#### **U.S. PATENT DOCUMENTS**

Copies of U.S. Patent documents do not need to be provided, unless requested by the Patent and Trademark Office. For patents, provide the patent number and the issue date. For published U.S. applications, provide the publication number and the publication date. For unpublished pending patent applications, provide the application number and the filing date.

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
		6,020,351	02/01/2000	Pero
<del> </del>		6,258,855	07/10/2001	Lorenz et al.
		6,265,450	07/24/2001	Asami et al.
		6,277,417	08/21/2001	Anderson
		6,310,090	10/30/2001	Hayek
. ,		6,344,214	02/05/2002	Lorenz
		6,433,025	08/13/2002	Lorenz

## FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Country	Number	<b>Publication Date</b>	Name of Applicant or Patentee	
		WIPO	WO 01/24787 A1	04/12/2001	Astacarotene AB	
		WIPO	WO 01/72296 A1	10/04/2001	Astacarotene AB	
Examiner's Initials*	Cite No. (optional)		OTHER DOCUMENTS			
		1		the immune response	of Helicobacter pylori.," Clin.	
		\	Microbiol. Infect., 8:438-441 (2002).			
			BASKIN et al., "Effects of dietary antioxidant supplementation on oxidative damage and			
			resistance to oxidative damage during prolonged exercise in sled dogs," Am. J. Vet. Res.,			
		61:886-891 (2000).				
		1	CARDOUNEL et al., "Direct superoxide anion scavenging by a disodium disuccinate			
		1	astaxanthin derivative: relative efficacy of individual stereoisomers versus the statistical			
		mixture of stere	coisomers by electron	paramagnetic resona	nce imaging," Biochem.	
	<u></u>	Biophys. Res. C	Commun., 307:704-712	2 (2003).		

EXAMINER	DATE
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Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS
		CHEW et al., "A Comparison of the Anticancer Activities of Dietary $\beta$ -Carotene,
		Canthaxanthin and Astaxanthin in Mice in Vivo," Anticancer Res., 19:1849-1854 (1999).
		CHEW et al., "Dietary $\beta$ -Carotene and Astaxanthin but not Canthaxanthin Stimulate Splenocyte Function in Mice," <i>Anticancer Res.</i> , 19:5223-5228 (1999).
		CHEW et al., "Dietary β-Carotene Stimulates Cell-Mediated and Humoral Immune Response in Dogs," J. Nutri., 130:1910-1913 (2000).
		CHEW et al., "Astaxanthin Stimulates Immune Response in Humans in a Double-Blind
		Study," Supply Side West International Trade Show, Venetian Hotel, Las Vegas, Nevada (10/2/2003).
		CHEW et al., "Carotenoid Action on the Immune Response," J. Nutri., 134:257S-261S (2004).
		COLLINS et al., "Serum carotenoids and oxidative DNA damage in human lymphocytes," <i>Carcinogenesis</i> , 19:2159-2162 (1998).
		COLLINS et al. "Biochemical and Biomedical Aspects of Oxidative Modification," Biochem. Soc. Trans., 29:337-341 (2001).
		GRADELET et al., "Dietary carotenoids inhibit aflatoxin B <sub>1</sub> -induced liver preneoplastic foci and DNA damage in the rat: Role of the modulation of aflatoxin B <sub>1</sub> metabolism," <i>Carcinogenesis</i> , 19:403-411 (1998).
		GROSS et al., "Cardioprotection and myocardial salvage by a disodium disuccinate astaxanthin derivative ( <i>Cardax</i> <sup>TM</sup> )," <i>Life Sci.</i> , 75:215-224 (2004).
<b>J</b>		HALLIWELL, "Why and how should we measure oxidative DNA damage in nutritional studies? How far have we come?," Am. J. Clin. Nutr., 72:1082-1087 (2000).
		JYONOUCHI, "Antitumor Activity of Astaxanthin and Its Mode of Action," Nutr. Cancer, 36:59-65 (2000).
		LESLIE, "Astaxanthin Cuts Carpal Tunnel, Arthritis Pain," November 05, 2002, Volume 38, Issue 40.
		LOFT et al., "Experimental study of oxidative DNA damage," Free Radic. Res., 29:525-539 (1998).
		LOFT et al., "Antioxidant Intervention Studies Related to DNA Damage, DNA Repair and Gene Expression," Free Rad. Res. 33:S67-83 (2000).
		LYONS et al., "Modulatory effects of an algal extract containing astaxanthin on UVA-irradiated cells in culture," <i>J. Dermatol. Sci.</i> , 30:73-84 (2002).
		MAYNE, "Antioxidant Nutrients and Chronic Disease: Use of Biomarkers of Exposure and Oxidative Stress Status in Epidemiologic Research," <i>J. Nutri.</i> , 133:933S-940S (2003).

EXAMINER SIGNATURE:	DATE CONSIDERED:	
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		MØLLER et al., "Oxidative DNA damage in human white blood cells in dietary
		antioxidant intervention studies," Am. J. Clin. Nutr., 76:303-310 (2002).
		NAGUIB, "Antioxidant Activities of Astaxanthin and Related Carotenoids," J. Agric. Food Chem., 48:1150-1154 (2000).
		NAITO et al., "Prevention of diabetic nephropathy by treatment with astaxanthin in diabetic db/db mice," <i>Biofactors</i> , 20:49-59 (2004).
		O'CONNOR et al., "Modulation of UVA light-induced oxidative stress by $\beta$ -carotene, lutein and astaxanthin in cultured fibroblasts," <i>J. Dermatol. Sci.</i> , 16:226-230 (1998).
		OHGAMI et al., "Effects of Astaxanthin on Lipopolysaccharide-Induced Inflammation In Vitro and In Vivo," <i>Invest. Ophthalmol. Vis. Sci.</i> , 44:2694-2701 (2003).
		PARK et al., "Dietary Lutein from Marigold Extract Inhibits Mammary Tumor Development in BALB/c Mice," J. Nutri., 128:1650-1656 (1998).
		SARETZKI et al., "MitoQ counteracts telomere shortening and elongates lifespan of fibroblasts under mild oxidative stress," <i>Aging Cell</i> , 2:141-143 (2003).
		SAVOURE et al., "Vitamin A status and metabolism of cutaneous polyamines in the hairless mouse after UV irradiation: action of beta-carotene and astaxanthin," <i>Int. J. Vitam. Nutr. Res.</i> , 65:79-86 (1995).
		SERRA et al., "Extracellular Superoxide Dismutase Is a Major Antioxidant in Human Fibroblasts and Slows Telomere Shortening," <i>J. Biol. Chem.</i> , 278:6824-6830 (2003).
		SPILLER et al., "Safety of an Astaxanthin-Rich <i>Haematococcus pluvialis</i> Algal Extract: A Randomized Clinical Trial," <i>J. Med. Food</i> , 6:51-56 (2003).
		TORBERGSEN et al., "Recovery of human lymphocytes from oxidative DNA damage; the apparent enhancement of DNA repair by carotenoids is probably simply an antioxidant effect," Eur. J. Nutr., 39:80-85 (2000).
		VON ZGLINICKI, "Oxidative Stress Shortens Telomeres," <i>Trends Biochem. Sci.</i> , 27:339-344 (2002).
		WIENER et al., "Astaxanthin from the Microalga Haematococcus - a superb natural antioxidant for human health," <i>Innovations in Food Technology</i> , 5 pages, beginning at page 22 (November 2003).
		ZSILA et al., "Interaction of the Disodium Disuccinate Derivative of <i>meso</i> -Astaxanthin with Human Serum Albumin: From Chiral Complexation to Self-Assembly," <i>Bioorg. Med. Chem. Lett.</i> , 13:4093-4100 (2003).

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<sup>\*</sup> Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		ØSTERLE et al., "Blood appearance and distribution of astaxanthin E/Z isomers among plasma lipoproteins in humans administered a single meal with astaxanthin," presented at 12 <sup>th</sup> International Symposium on Carotenoids, Cairns, Queensland, Australia, July 18-25, 1999 (Abstract).
		PARK et al., "Immune Stimulating Action of Dietary Astaxanthin in Humans," FASEB J. 18:A479 (2004) (Abstract).
		LANDRUM, "Functions of B-Cryptoxanthin, Astaxanthin, Lutein, and Zeaxanthin in Humans,"
		http://www.nutrilite.com/english/IBO/Research/ScientificCredibility/NutritionResearch/doc2159r.asp, printed from internet 7/19/2004, © Nutrilite, 2003 Access Business Group LLC.
		"Astaxanthin, Nature's Super Carotenoid," <i>BioAstin™ Technical Bulletin #062</i> , pp. 1-19, http://www.cyanotech.com/pdfs/bioastin/batl11.pdf (2000).
		"Nomenclature and Structure," <a href="http://dcb-carot.unibe.ch/nomen.htm">http://dcb-carot.unibe.ch/nomen.htm</a> (2004).
		"Comet Assay: the analysis of DNA damage with single cell gel electrophoresis," Department of Biochemistry, The Chinese University of Hong Kong, ENS 4510 Methods in Toxicological Research Laboratory, http://www.bch.cuhk.edu.hk/webct//ens4310/kmc/Comet Assay.html (2004).
		"Antioxidant Properties of Astaxanthin," <a href="http://www.astaxanthin.org/antiox-prop.htm">http://www.astaxanthin.org/antiox-prop.htm</a> (2004).
		"Astaxanthin and Health and Wellness in Animals," http://www.astaxanthin.org/wellness.htm (2004).
		"Carotenoids," http://www.astaxanthin.org/carotenoids.htm (2004).
		"Haematococcus pluvialis Algal Meal Produced With Mera Pharmaceuticals' Proprietary Technology: A Unique Source of Natural Astaxanthin and Algal Nutrients," <a href="http://www.astafactor.com/techreports/tr3004-001.htm">http://www.astafactor.com/techreports/tr3004-001.htm</a> (2004).
		Dr. Weil's Select Formulas Energy Solution, Includes Dr. Weil's Multivitamin & Antioxidant, http://www.drugstore.com/products/prod.asp?pid=84925&catid=52795&trx=PLST-0-
		SEARCH&trxp1=52795&trxp2=84925&trxp3=1&trxp4=0&btrx=BUY-PLST-0- SEARCH (2004).
		ZANTHIN® 4 mg Astaxanthin Complex Vegetarian Softgel, Product Specification, Product F0241, U.S. Nutra, 2751 Nutra Lane, Eustis, FL 32726, <a href="https://www.usnutra.com">www.usnutra.com</a> (2004).

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